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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,458	10/02/2001	Jan Seppala	S63.2-10087	9618

490 7590 02/27/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,458

Applicant(s)

SEPPALA ET AL.

Examiner

Sarah K Webb

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 1/29/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. This is in reference to provisional application number 60/238795.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1,7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No.5,445,646 to Euteneuer et al.

Euteneuer discloses a stent delivery catheter in Figure 2 that includes all the limitations of claims 1 and 7-10. A catheter has a stent mounted on the catheter, and two overlapping sleeves (14,16) surround the stent (17). The first end of the proximal sleeve (14) is attached to the catheter (12) proximally of the stent, while the distal end of the

Art Unit: 3731

distal sleeve (16) is attached to the catheter (12) distally of the stent (17). Euteneuer explains that a balloon can be included on the catheter to inflate and expand the stent (column 9, lines 65-67).

3. Claims 1,2, and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,968,069 to Dusbabek et al.

Dusbabek discloses a stent deliver catheter (26) in Figures 15 and 16 that has an inflatable stent mounting region, or balloon (14). This embodiment is described in column 12, lines 1-20). Although not shown, a stent is disposed about the stent mounting region, and is capable of moving from an unexpanded position to an expanded position (see rest of document). A stent retaining sleeve (108) is attached to the catheter “about” a portion of the stent. The sleeve retracts slightly when the stent is expanded. The sleeve could be described as both pleated and ribbed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,4,5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,350,278 to Lenker et al. in view of Euteneuer et al.

Lenker discloses a stent delivery catheter that includes a stent mounting region and restraining sheath. Lenker fails to include an inflatable portion, or balloon, in the

Art Unit: 3731

stent mounting region. Euteneuer teaches that a self-expanding stent delivery catheter with a retaining sleeve can alternately be used to deliver a balloon expandable stent.

Euteneuer teaches that it is well known in the art to include a balloon on a catheter for stent expansion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an inflatable portion on the catheter of Lenker, as taught by Euteneuer, as it is well known in the art to use a balloon to expand a stent.

Regarding claim 4, Lenker shows various embodiments where the sheath has a plurality of openings. One is shown in Figure 11 - a sheath (100) that has a plurality of openings defined between members (104) that allow the sheath to spread as the stent expands. Another is shown in Figures 23A and 23B - openings are defined between the separable members (342). Lastly, an embodiment in Figures 24A-C includes a perforation (364), which is inherently a plurality of small openings.

Regarding claims 5 and 6, the embodiment shown in Figures 21A and 21B shows a sheath that has alternating strips of two materials. One strip is member 302 and is made of a flexible polymeric material (column 9, lines 61-63). The other strip 304 is described as a wire (column 11, line 45), which is interpreted to mean that it is made from a metallic material.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,964,730 to Williams discloses a perforated sheath. US 6,033,380 to Butaric et al. discloses a pleated sleeve. US 6,168,617 to Blaeser et al. discloses sheath with multiple openings (Fig.4). US 6,254,628 to Wallace discloses non-slipping stent restraining sheaths.

Art Unit: 3731

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

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February 21, 2003


Michael Milano
Supervisory Patent Examiner
Art Unit 3700